Remarks

The Office Action dated April 28, 2008 has been carefully reviewed and the following comments are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Applicants have amended claims 18, 19, 23, 26, 31, 41, 42 and 44. Without acquiescing to the merits of any rejection or objection, Applicants have amended claims as suggested by the Examiner. No new matter has been added by this amendment.

Applicants respectfully submit that the pending claims are at least in part supported by the disclosure of U.S. Provisional Application 60/331,231 and where applicable are entitled to the priority date of that application.

The Claim Objections should be withdrawn

Without acquiescing to the merits of the objection and for the sole purpose of advancing prosecution, Applicants have amended claims 18, 19, 26, and 42 as requested by the Examiner thereby rendering the claim objection moot.

The Rejections under 35 U.S.C. 103(a) should be withdrawn

Claims 16 to 19 were rejected under 35 U.S.C. 103(a) as allegedly being obvious over (1) Lambert *et al.*, (2) Young *et al.*, (3) Bossart *et al.*, (4) Genbank Accession AF 212302 and (5) Wang *et al.*

Specifically, the Examiner alleges it would have been obvious to one of skill in the art to modify the methods taught by Young *et al.* and Lambert *et al.* to inhibit paramyxovirus fusion. The Examiner further alleges that reasonable expectation of success would be based on the disclosure of Bossart *et al.* and the disclosure of the HeV sequence in Genbank.

Applicants respectfully disagree. For the reasons set forth below, the Bossart *et al.* article is not available as prior art and therefore cannot be relied upon as the basis for a rejection under 35 U.S.C. 103(a). With Bossart *et al.* unavailable as prior art, the remaining reference alone or in combination are deficient; for example, absent the disclosure of Bossart *et al.* there would be no reasonable expectation of success (*see* page 5 of the Office Action). Thus, without the disclosure of Bossart *et al.*, the claims are clearly not obvious.

Prior to discussing the merits of the rejection, Applicants note the Office Action fails to discuss Wang *et al.* In the absence of any indication to the contrary, Applicants nevertheless assume that Wang *et al.* was factored into the analysis under 35 U.S.C. 103(a).

The Bossart *et al.* article is not available as prior art and therefore the reference cannot be relied upon for the rejections under 35 U.S.C. 103(a). Applicants respectfully submit that the Bossart *et al.* reference, co-authored by the inventors, Katherine N. Bossart and Christopher C. Broder, as well as Lin-Fa Wang and Bryan T. Eaton, was first publicly available on November 15, 2001. Lin-Fa Wang and Bryan T. Eaton are only co-authors of the publication and not co-inventors. The instant application is a U.S. National Stage application of PCT application PCT/US02/36283, filed November 13, 2002, which claims priority to U.S. Provisional Application 60/331,231 filed on November 13, 2001. Thus, the Bossart *et al.* reference published after the filing of the U.S. Provisional Application but less than one year before the filing of the PCT application. To the extent the claims are supported by the U.S. Provisional Application, the Bossart *et al.* reference is not prior art to that subject matter. In addition, to the extent that the pending claims are supported by the disclosure of the PCT application, the Bossart *et al.* reference is also not prior art to that subject matter. Applicants submit herewith declarations under 37 C.F.R. 1.131 establishing that the inventors conceived the subject matter of the instant application prior to November 15, 2001 (the effective date of the reference). In their declaration, Applicants also respectfully submit that they are the sole inventors since Lin-Fa Wang and Bryan T. Eaton did not contribute to the conception of the invention. As the Examiner is aware, a declaration by Applicants indicating that the Applicants are the sole inventors and that any other author was merely working under their direction is sufficient to remove the publication as a reference under 35 U.S.C. 102(a) (*see* M.P.E.P. 715.01(c)). The Bossart *et al.* reference is not available as prior art as it was co-authored by the inventors as well as individuals merely working under their direction, it published less than one-year prior to the filing of PCT application PCT/US02/36283 and the inventors conceived the subject matter of the instant application prior to the publication of the reference.

Without the disclosure of Bossart *et al.*, the claims are not obvious over the cited references because the remaining references do not disclose or suggest all the elements of the claims. Lambert *et al.* discloses synthetic peptides derived from separate domains with HIV-1 transmembrane protein which are potent inhibitors of HIV-1 infection and fusion (*see* Lambert *et al.*, p. 2186, Abstract). The Office Action indicates that this reference discloses identification of conserved heptad regions of these peptides in respiratory syntical virus, human parainfluenza virus type 3 (HPIV-3) and measles virus and that these

peptides derived from the fusion proteins of these viruses blocked fusion of virus with a cell (*see* page 4 of the Office Action). The Office Action further indicates that Young *et al.* discloses a peptide derived from Newcastle disease virus fusion protein (F), which also inhibits fusion of the Newcastle disease virus (*see* page 4 of the Office Action). Neither of these references discloses or suggests use of peptides derived from Hendra and Nipah virus F protein to inhibit cell fusion or to induce an immune response. Nor do any of these references disclose or suggest the claimed peptides.

Wang *et al.* discusses the molecular biology of Hendra and Nipah viruses (*see* Wang *et al.*, p. 279, Abstract). Importantly, Wang *et al.* notes that there is no significant homology between HeV and NiV genomes and other members of the *Paramyxovirinae* and that only a limited sequence homology can be found at the protein level (page 282, column 1). Particularly, Wang *et al.* note that the homology detected by Nipah, Hendra and other viruses of the genus was lower than that observed among most existing members within any single genus (page 285, column 2). Wang *et al.* further note that the genomic features suggest that HeV and NiV are significantly different from members of the three existing genera within the subfamily (page 285, column 2). Given these differences, Wang *et al.* suggest that Nipah and Hendra virus should be considered a new genus within *Paramyxovirinae* (*see* page 286, column 1). In addition, Wang *et al.* discloses numerous other differences between HeV and NiV and other member of *Paramyxovirinae.* While generally, proteins of HeV and NiV have similarity in size, sequence and/or predicted functional domain structures to those of respiroviruses and morbilliviruses (*see* page 282, column 1), the F proteins of HeV and NiV have many unique properties (*see* page 283 to 294). Given these differences, those of skill in the art would not be motivated to combine the disclosures of Lambert *et al.* and Young *et al.* and apply it to HeV and NiV; also there would be no reasonable expectation of success.

Since the Bossart *et al* reference is not available as prior art, it cannot be the basis of an obviousness rejection. The remaining references do not remedy the deficiencies of Bossart *et al.*; absent the disclosure of Bossart *et al.* there is no reasonable expectation of success (*see* page 5 of the Office Action). Thus, Applicants request withdrawal of this rejection.

The Rejections under 35 U.S.C. 112 should be withdrawn

Claims 23 to 26 and 31 to 46 were rejected under 35 U.S.C. 112, first paragraph, for allegedly lacking enablement. Claims 23 to 26 and 44 were rejected under 35 U.S.C., second paragraph, for lack of definiteness. Applicants respectfully disagree.

Specifically, the Office Action alleges that the specification, while enabling for inhibiting paramyxovirus viral infection *in vitro*, does not provide enablement for treatment or prevention of paramyxovirus viral infection by administration of SEQ ID NO: 1 and/or SEQ ID NO: 2. Applicants respectfully disagree. As the Examiner is aware, the test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation. *See In Wands*, 858 F.2d 721, 737 (Fed. Cir. 1988). Compliance with the enablement requirement does not turn on whether an example is disclosed (*see* M.P.E.P. 2164.02).

Without acquiescing to the merits of any rejection and for the sole purpose of advancing prosecution, claims 23 and 31 were amended to recite methods of inducing an immune response. The amended claims are clearly enabled; in particular, one of skill in the art would be able to use peptides in the claimed methods without undue experimentation. The specification discloses the claimed peptides, isolation and construction of the peptides (*see e.g.*, specification, page 23, line 1 to page 23, lines 12) as well as methods of using the peptides (*see e.g.* specification, page 6 line 4 to page 7, line 2; page 17, lines 18 to 24; page 19, lines 19 to 25; Examples, page 21, line 15 to page 27, line 5). The claimed soluble HeV and NiV F proteins induce an immune response by their ability to prevent viral fusion with the cells; the specification discloses that the claimed peptides can inhibit fusion of HeV and NiV (page 24, lines 1 to 5; *see also* page 17, line 22 (fusion of virus essential step in infection)). Furthermore, while the enablement requirement does not turn on the presence of working examples (M.P.E.P. 2164.02) and certainly does not require *in vivo* clinical studies, the specification also discloses *in vitro* studies. Specifically, the specification discloses the results of *in vitro* studies on the effects of administration of peptides according to the instant invention (*see* page 25, line 15 to page 27, line 15) on HeV infection. In addition, the Office Action indicates a paramyxovirus subunit vaccine has been shown to induce immune responses in mammals (*see* page 6 of the Office Action). For the reasons set forth above, the claims are enabled.

Without acquiescing to the merits of the rejection and for the sole purpose of advancing prosecution, Applicants have amended claims 23 and 44 thereby rendering alleged lack of definiteness rejection moot.

In light of the foregoing remarks and amendments, Applicants respectfully request withdrawal of the rejections under 35 U.S.C 112.

Conclusion

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any necessary fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17, which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

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Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
202-739-3000

Respectfully submitted,
Morgan, Lewis & Bockius LLP

Robert Smyth
Registration No. 50,801